Application Number 10/723,316
Responsive to Office Action mailed April 7, 2006

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1 (Currently Amended): A method for treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia in a patient, comprising:

providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia in the patient;

providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of ~~a sacral nerve or branches or portions thereof, a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof,~~ a sacral splanchnic nerve or branches or portions thereof, ~~a pelvic splanchnic nerve or branches or portions thereof,~~ the prostate or branches or portions thereof, ~~the pelvic floor, the colon or branches or portions thereof,~~ the bladder or portions thereof, the vagina or portions thereof, ~~the anus or portions thereof, the external anal sphincter or portions thereof,~~ the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;

implanting the first lead in tissue of the patient adjacent, around or in one of ~~the sacral nerve or branches or portions thereof, the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof,~~ the sacral splanchnic nerve or branches or portions thereof, ~~the pelvic splanchnic nerve or branches or portions thereof,~~ the prostate or branches or portions thereof, ~~the pelvic floor, the colon or branches or portions thereof ,~~ the bladder or portions thereof, the vagina or portions thereof, ~~the anus or portions thereof, the external anal sphincter or portions thereof,~~ the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof[[,]];

operably connecting the proximal end of the at least first lead to the implantable pulse generator;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, sexual dysfunction, orgasmic dysfunction, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia.

Claim 2 (Original): The method of claim 1, wherein the at least first lead is selected from the group consisting of a unipolar lead, a bipolar lead, a tri-polar lead, a quadrapolar lead, and a multi-polar lead.

Claim 3 (Original): The method of claim 1, wherein the at least first lead is selected from the group consisting of a beam steering lead comprising multiple electrodes and a lead comprising multiple electrodes disposed in an areal pattern on a planar or curved surface.

Claim 4 (Original): The method of claim 1, wherein the at least first lead is selected from the group consisting of a cuff lead, a paddle lead, a tined lead, a lead having an active fixation device or member disposed thereon, attached thereto or forming a portion thereof.

Claim 5 (Currently Amended): The method of claim 1, wherein the at least first lead ~~is~~ includes a fixation device or member selected from the group consisting of a suture sleeve, a barb, a helical screw, a hook and a tissue in-growth mechanism.

Claim 6 (Original): The method of claim 1, wherein the at least first lead further comprises one or more electrodes configured to operate in conjunction with an electrically conductive portion of the implantable pulse generator acting as an indifferent electrode.

Claim 7 (Original): The method of claim 1, further comprising providing, implanting, operably connecting and delivering electrical stimuli from a second implantable medical electrical lead configured for implantation adjacent, around or in at least one of a sacral nerve or branches or portions thereof, a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof and a prostatic plexus nerve or branches or portions thereof of the patient, wherein the second lead comprises proximal and distal ends and at least one electrode.

Claim 8 (Original): The method of claim 7, further comprising delivering the electrical pulses through tissue disposed between the electrodes located on the first and second leads.

Claim 9 (Original): The method of claim 1, wherein the electrical stimulation pulses that are delivered to the desired nerve target sites or portions cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode.

Claim 10 (Original): The method of claim 1, further comprising providing a lead extension, operably connecting same between the proximal end of the at least first lead and the implantable pulse generator, and delivering the electrical stimulation pulses through the lead extension.

Claim 11 (Original): The method of claim 1, wherein the first lead is selected from the group consisting of a lead comprising a lead body less than about 5 mm in diameter, a lead comprising a lead body less than about 1.5 mm in diameter, a lead having a lead body comprising polyurethane or silicone, a lead comprising electrical conductors disposed within the body thereof and extending between the proximal and distal ends of the lead wherein the conductors are formed of coiled, braided or stranded wires, and a lead comprising at least one ring electrode, at least one coiled electrode, at least one button electrode, at least one electrode formed from a portion of wire, a barb or a hook, a spherically-shaped electrode, and a helically-shaped electrode.

Claim 12 (Original): The method of claim 1, wherein an inter-electrode distance of the first lead is selected from the group consisting of about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, about 10 mm, about 12 mm, about 14 mm, about 16 mm, about 18 mm, about 20 mm, about 25 mm, and about 30 mm.

Claim 13 (Original): The method of claim 1, wherein the at least one electrode of the first lead has an electrode surface area ranging between about 1.0 sq. mm and about 100 sq. mm, between about 2.0 sq. mm and about 50 sq. mm, or between about 4.0 sq. mm and about 25 sq. mm.

Claim 14 (Original): The method of claim 1, wherein the distance between the proximal and distal ends of the at least first lead is selected from the group consisting of less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches.

Claim 15 (Original): The method of claim 1, wherein the implantable pulse generator comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture.

Claim 16 (Original): The method of claim 1, further comprising providing an external programming unit and effecting telemetric communication between the programming unit and the implantable pulse generator.

Claim 17 (Original): The method of claim 1, wherein the implantable pulse generator further comprises at least one of a primary battery power source and a secondary battery power source.

Claim 18 (Original): The method of claim 1, wherein the implantable pulse generator is configurable so as to permit at least one of the frequency, rate, amplitude, phase, width and morphology of the pulses generated and delivered thereby to be varied programmably by a user.

Claim 19 (Original): The method of claim 1, wherein the at least first lead is configured for percutaneous introduction and implantation within the patient.

Claim 20 (Original): The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having frequencies ranging between about 50 Hz and about 100 Hz, between about 10 Hz and about 250 Hz, and between about 0.5 Hz and about 500 Hz.

Claim 21 (Original): The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having amplitudes ranging between about 1 Volt and about 10 Volts, between about 0.5 Volts and about 20 Volts, and between about 0.1 Volts and about 50 Volts.

Claim 22 (Original): The method of claim 1, wherein the implantable pulse generator and the at least first lead are capable of generating and delivering electrical pulses having pulse widths ranging between about 180 microseconds and about 450 microseconds, between about 100 microseconds and about 1000 microseconds, and between about 10 microseconds and about 5000 microseconds.

Claim 23 (Currently Amended): The method of claim 1, wherein the implantable pulse generator ~~and the at least first lead and at least a second lead are capable of generating and delivering~~ generates electrical pulses having varying spatial or temporal phases for respective delivery to the first lead and at least a second lead.

Claim 24 (Original): The method of claim 1, wherein the electrical stimulation pulse regime provided to the patient is effective in providing at least one of urinary urgency relief and urinary frequency relief.

Claim 25 (Original): The method of claim 1, wherein the electrical stimulation pulse regime provided to the patient is effective in providing relief from sexual dysfunction.

Claim 26 (Currently Amended): The method of claim 1, further comprising concomitantly delivering a drug to the patient and delivering the electrical stimulation regime.

Claim 27 (Currently Amended): The method of claim ~~22~~ 26, further comprising providing, implanting and activating an implantable drug pump for providing the drug to the patient.

Claim 28 (New): A method for treating at least one of urinary voiding dysfunction, urge frequency disorder, or urinary retention disorder in a patient comprising:

providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of urinary voiding dysfunction, urge frequency disorder, or urinary retention disorder in the patient;

providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof , the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;

implanting the first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof , the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof;

operably connecting the proximal end of the at least first lead to the implantable pulse generator;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from at least one of urinary voiding dysfunction, urge frequency disorder, or urinary retention disorder.

Claim 29 (New): The method of claim 28,

wherein providing at least a first implantable medical electrical lead comprises providing the first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the pudendal nerve or branches or portions thereof, and

wherein implanting the first lead comprises implanting the first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof.

Claim 30 (New): A method for treating at least one of pelvic pain, prostatitis, prostatalgia or prostatodynia in a patient, comprising:

providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of pelvic pain, prostatitis, prostatalgia or prostatodynia in the patient;

providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof , the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser

sciatic foramen or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;

implanting the first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof, the hypogastric nerve or branches or portions thereof, the prostatic plexus nerve or branches or portions thereof, the sacral splanchnic nerve or branches or portions thereof, the pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof , the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof;

operably connecting the proximal end of the at least first lead to the implantable pulse generator;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from at least one of pelvic pain, prostatitis, prostatalgia or prostatodynia,

wherein the electrical stimulation pulses that are delivered to the desired nerve target sites or portions cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode.

Claim 31 (New): The method of claim 30,

wherein providing at least a first implantable medical electrical lead comprises providing the first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the pudendal nerve or branches or portions thereof, and

wherein implanting the first lead comprises implanting the first lead in tissue of the patient adjacent, around or in one of the pudendal nerve or branches or portions thereof.

Claim 32 (New): A method for treating at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia in a patient, comprising:

providing an hermetically sealed implantable electrical pulse generator configured to provide at least one electrical stimulation pulse regime effective to treat at least partially at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia in the patient;

providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in a pudendal nerve or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode;

implanting the first lead in tissue of the patient adjacent, around or in the pudendal nerve or branches or portions thereof;

operably connecting the proximal end of the at least first lead to the implantable pulse generator;

implanting the implantable pulse generator within the patient; and

delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from at least one of urinary voiding dysfunction, fecal voiding dysfunction, constipation, incontinence, urge frequency disorder, urinary retention disorder, erectile dysfunction, pelvic pain, prostatitis, prostatalgia and prostatodynia.